JUN 13 2001

510(k) SUMMARY

SUBMITTED BY

Prosie Rey-Fessler, RAC
Director, Quality Assurance and Regulatory Affairs
Interpore Cross International
181 Technology Drive
Irvine, California 92618

April 13, 2001

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME
Classification Name: Conventional Hemodialyzer
Common/Usual Name: Ultrafiltrator or UltraConcentrator
Product Classification: Class II
Proprietary Name: UltraConcentrator™ System

PREDICATE DEVICE
The predicate device is the UltraCon™ Ultrafiltrator Permeability Hemodialyzer which was previously cleared under 510(k) K981253 dated December 11, 1998.

INDICATIONS-FOR-USE
The UltraConcentrator™ System is indicated for use as an ultrafiltrator for the selective removal of undesirable plasma water and small dissolved solutes from blood plasma proteins and formed cellular elements, as may be present in cases of acute hemodilution such as following cardiopulmonary bypass.

DEVICE DESCRIPTION
The UltraConcentrator System is an ultrafiltration device that is used to remove plasma water from dilute blood plasma proteins, increasing the concentration of plasma proteins and formed cellular elements. The UltraConcentrator filter is constructed of semi-permeable hollow fibers, which divide the device into two compartments. An inner pathway for diluted blood perfusate consists of the inlet and outlet connectors and flow dispersion headers, which are connected through the inner lumen of semipermeable hollow fiber membranes. When perfusate fluid passes through the inner diameter of the hollow fibers, water and small dissolved solutes can pass through the semi-permeable membrane walls into the annular ultrafiltrate waste compartment and then be discarded. The UltraConcentrator filter is intended to be used with the peristaltic pump system.

COMPARISON TO THE PREDICATE DEVICE

The intended use and the fundamental scientific technology of the device remain the same.

SUMMARY OF TESTING

Based on the testing and the risk analysis conducted on the device, the modified device has been demonstrated to be substantially equivalent to the predicate device. Therefore, Interpore Cross International believes that sufficient evidence exists to reasonably conclude that this device is substantially equivalent to the existing legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Prosie Rey-Fessler, RAC
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181 Technology Drive
IRVINE CA 92618

Re: K011148
UltraConcentrator™ System
Dated: May 11, 2001
Received: May 14, 2001
Regulatory Class: II
21 CFR §876.5820/Procode: 78 FJI

Dear Ms. Rey-Fessler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K011148
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510(k) Number (if known): K011148

Device Name: UltraConcentrator™ System

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K011148

Prescription Use ✓ **OR** **Over-The-Counter Use**
(PER 21 CFR 801.109)

(Optional Format 1-2-96)